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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,214	05/26/1998	WALTER SCHMIDT	0652.1710000	5745

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/077,214	SCHMIDT ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-55 and 59-70* is/are pending in the application.

4a) Of the above claim(s) *37,41,45-47,51-55 and 59-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,38-40,42-44,48-50,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/2003 has been entered.

2. Claims 36,38-40,42-44,48-50,69,70 are under consideration.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 36,38-40,42-44,48-50,69,70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nair et al. in view of Fearon et al., Townsend et al., Van Der Bruggen et al. and prior art disclosed in the specification (see page 3) for the reasons elaborated in the previous Office Action.

Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells (see abstract). The organic polycation used by Nair

et al. contains polylysine conjugated to another molecule (see abstract and page 238, second column, last paragraph). Nair et al. teach that said method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I (see page 242, last sentence). Nair et al. do not disclose human tumor cells treated to express influenza virus peptide in the context of HLA class I. Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA (see entire paper). HA is a viral antigen. Townsend et al. teach that influenza HA or NP peptides are recognized by CTL in the context of MHC class I. Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo (see page 15, second paragraph). Van Der Bruggen et al. teach that said peptides can be delivered by vector (to infect APC) or by direct administration of the peptide to APC (see page 15, second paragraph). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Nair et al. disclose use of an organic polycation (eg. cationic liposomes containing polylysine) to deliver an MHC class I antigen to tumor cells, Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA while Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo. In view of the fact that the cells disclosed by Nair et al. were treated with intact protein, said cells would have been expected to present multiple different peptides representing different epitopes derived from said molecule. It would also be expected that HA would encode a variety of different epitopes that would bind different HLA molecules found on MHC antigen heterozygous human tumor cells. One of ordinary skill in the art would have been motivated to do the aforementioned because of the demonstration by Fearon et al. of the use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I. Regarding the "allogeneic" tumor vaccine limitation, the recitation of an intended use (eg. delivery to an allogeneic host) carries no patentable weight in this product claim. Fearon disclose use of cell lines expressing a foreign antigen for immunization (see abstract). Regarding the limitation of claim 70, the recitation of a method wherein the claimed product is made carries no

patentable weight in the instant product claims because the claimed product appears to be the same irregardless of how it is made (eg. loaded with peptide via incubation with polylysine versus loaded with peptide via incubation with transferrin/polylysine).

Regarding applicants comments about Nair et al. and MHC binding by the peptide, the recitation of a method wherein the instant product is made carries no patentable weight in the instant product claims because the prior art product rendered obvious in the instant rejection is the same as the claimed invention. While Nair et al. initially add full length protein, *Nair et al. discloses that said protein is internalized into the cell and processed to yield peptides which bind MHC class I (eg. see Nair et al., abstract and column two, page 241, Discussion section, continued on next page).* Regarding motivation to create the claimed invention, one of ordinary skill in the art would have been motivated to do the aforementioned because of the demonstration by Fearon et al. of the use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I. Nair et al. and Fearon et al. both teach that the immunogenicity of tumor cells can be increased by adding additional exogenous antigens to said tumor cells. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success of producing the claimed invention because *Fearon et al. teach use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I.* While Nair et al. do not disclose human tumor cells treated to express influenza virus peptide in the context of HLA class I, Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA (see entire paper). HA is a viral antigen. Townsend et al. teach that influenza HA or NP peptides are recognized by CTL in the context of MHC class I. Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo (see page 15, second paragraph). Van Der Bruggen et al. teach that said peptides can be delivered by vector (to infect APC) or by direct administration of the peptide to APC (see page 15, second paragraph). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed

invention because Nair et al. disclose use of an organic polycation (eg. cationic liposomes containing polylysine) to deliver an MHC class I antigen to tumor cells, Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA while Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo.

6. No claim is allowed.

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday through Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644